



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,643	11/20/2001	Michel G. Bergeron	480844.90010	1147

26710 7590 07/08/2003

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,643	BERGERON ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 46-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 46-52, 63-65, and 82-86, drawn to a method using probes and/or amplification primers (claims 46-52 and 63-65) and a diagnostic kit (claims 82-86).

Group II, claims 53, 56, 60, 71, 72, 76, 77, 79, and 80, drawn to a method for the detection, identification and/or quantification of a microorganism (claim 53), a method for detecting the presence and/or amount of any bacterium directly from a test sample or a bacteria culture (claim 56), a method for detecting the presence and/or amount of any bacterium directly from a test sample or a fungal culture (claim 60), and a diagnostic kit (claims 71, 72, 76, 77, 79, and 80).

Group III, claims 54, 55, 57-59, 61, 62, 73-75, 78, 81, and 87-90, drawn to a method for detecting the presence and/or amount of a microorganism (claims 54 and 55), a method for detecting the presence and/or amount of any bacterium in a test sample (claims 57 and 58), a method for obtaining *tuf* sequences from any bacterium directly from a test sample or a bacterial culture (claim 59), a method for detecting the presence and/or amount of any fungus in a test

Art Unit: 1634

sample (claim 61), and a method for obtaining *tuf* sequences from any fungus directly from a test sample or a fungal culture (claim 59) and a diagnostic kit (claims 73-75, 78, 81, and 87-90).

Group IV, claims 66, drawn to a nucleic acid.

Group V, claims 67-70, drawn to an oligonucleotide (claim 67), a recombinant plasmid (claim 68), and a recombinant host (claims 69 and 70).

2. The inventions listed as Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: .

Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group II such as SEQ ID NOs: 26-36 is not required for Group I.

Groups I and III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group III such as SEQ ID NO: 1-24 is not required for Group I.

Groups I and IV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group IV such as SEQ ID NO: 26-36 is not required for Group I.

Groups I and V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group V such as SEQ ID NO: 1-25 is not required for Group I.

Art Unit: 1634

Groups II and III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group III such as step b) of claim 54 is not required for Group II.

Groups II and IV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group IV such as SEQ ID NO: 110-117 is not required for Group II.

Groups II and V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group V such as SEQ ID NO: 1-25 is not required for Group II.

Groups III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group III such as SEQ ID NO: 1-25 is not required for Group IV.

Groups III and V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group V such as SEQ ID NO: 26-36 is not required for Group III.

Groups IV and V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, search required for Group V such as SEQ ID NO: 1-25 is not required for Group IV.

3. Sequence Election Requirement Applicable to each groups

Groups I to V contain SEQ ID Nos. These sequence are structurally distinct chemical compounds and generally, are unrelated to one another. These sequences are thus deemed to

Art Unit: 1634

normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. In the absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*

Applicant is advised to select a single SEQ ID NO. The examination will be restricted to only elected SEQ ID NO and should not to be construed as a species election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

A handwritten signature in black ink, appearing to read 'Frank Lu', is written above the printed name.

Frank Lu
July 7, 2003